

Developments within the European Union Regarding Deca-BDE as Interpreted by Health and Ecology Staff October 12, 2005

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The European Union currently has two main laws which regulate the market and use of PBDEs in Europe. Directive 2003/11/EC of February 6, 2003, passed by the European Parliament and European Council, bans the marketing and use of Penta-BDE and Octa-BDE as of August 15, 2004.¹ In January 2003, the European Parliament and the Council of the European Union passed Directive 2002/95/EC, “**Restriction of certain Hazardous Substances to Electrical and Electronic Equipment (RoHS)**”, which lists the substances which are to be phased out of electrical and electronic equipment by July 1, 2006. The list includes Polybrominated Diphenyl Ether (PBDE) flame retardants, among them Penta-, Octa-, and Deca-BDE.

The Directive also states that the European Commission Joint Research Center (a research based policy support organization located within the European Commission) should evaluate applications for Deca-BDE to establish whether the Directive should be amended, i.e., certain applications of Deca-BDE should be exempted from the ban. The human health risk assessment was to be completed by France and the environmental risk assessment by the UK.

In February 2004, France completed the Human Health Draft of the Draft Update Risk Assessment for Deca-BDE within the framework of the Existing Substances Regulation (793/93 EEC). This portion of the risk assessment drew one conclusion on Deca-BDE, with regard to neurotoxicity. The Draft Update concluded that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already.²

In May 2004, the United Kingdom completed the Final Environmental Draft of the Draft Update Risk Assessment for Deca-BDE. It concluded that there is need for further information and/or testing with regard to the assessment of Deca-BDE to be persistent, bioaccumulative, and toxic. The study also concluded that further information and testing are necessary to monitor the possible formation of more toxic and bioaccumulative products that may result from the degradation of Deca-BDE. However, the study concluded that further risk reduction measures are not currently necessary for Deca-BDE.³

¹ Amendment 24 to Council Directive 76/769/EEC. Available at http://europa.eu.int/comm/enterprise/chemicals/legislation/markrestr/amendments_en.htm, viewed October 12, 2005.

² European Commission Joint Research Center, 2004. Update of the risk assessment of Bis(Pentabromophenyl) Ether (Decabromodiphenyl Ether): Human Health Draft of February 2004.

³ European Commission Joint Research Center, 2004. Update of the risk assessment of Bis(Pentabromodiphenyl) Ether (Decabromodiphenyl Ether): Final Environmental Draft of May 2004.

In March 2005, the Scientific Committee on Health and Environmental Risks (SCHER), a committee of physicians and professors who serve an advisory role within the European Commission, released their opinion on the May 2004 Environmental Risk Assessment completed by the UK. Although the SCHER states that the update is well done, they disagree with the recommendation that risk reduction measures are not currently necessary. The SCHER concludes that,

Emissions of DeBDE [Deca-BDE] to the environment may constitute serious problems in the future. If formation of lower brominated, bioaccumulating substances take place this process can go on for a very long time and there are no possibilities to stop it. The previous scientific committee (CSTEE⁴) said that the uncertainties in the fate of Deca-BDE warrant risk reduction measure. Today there is further evidence for degradation of this substance to potentially harmful compounds and SCHER also strongly recommends risk reduction measures (conclusion iii).⁵

Following the release of the SCHER opinion in March 2005, the European Commission Joint Research Center authored a second update to the May 2004 Environmental Risk Assessment. While disagreeing with the conclusion of the SCHER that further risk reduction measures are necessary, the report incorporates the SCHER's recommendations for a regular review of any new information relating to Deca-BDE.⁶ The report does discuss the need for further study of Deca-BDE, particularly the debromination of Deca-BDE to lower PBDE congeners which it cites as of "high concern" and notes that, "many of these substances [lower PBDE congeners] are considered to be "persistent, bioaccumulative, and toxic (PBT) or very persistent and very bioaccumulative (vPvB)."⁷

On April 19, 2005, the Technical Adaptation Committee for the RoHS Directive (a committee formed to make decisions on unresolved issues of the RoHS) met to vote on a draft Decision by the European Commission to exempt Deca-BDE from the RoHS Directive. Prior to the vote, some member states questioned whether a vote was appropriate due to continuing doubts regarding the environmental and human health impacts of Deca-BDE.⁸ Nevertheless the vote proceeded and the Draft Decision passed, although the vote fell short of a qualifying majority of 72.3% and was passed on to the European Parliament and Council for scrutiny on June 6, 2005.

The European Parliament, upon receiving the Draft Decision, questioned whether the Commission had exceeded its implementing powers, and charged the Commission with ignoring findings of the May 2004 Environmental Risk Assessment and the March 18, 2005 SCHER opinion. On June 21, 2005, Parliament's Committee on the Environment, Public Health and Food Safety then proceeded by voting in favor of a resolution calling for the European Council

⁴ CSTEE: European Commission's Scientific Committee on Toxicity, Ecotoxicity, and the Environment

⁵ SCHER, 2005. "Opinion on 'Update of the Risk Assessment of bis(pentabromophenyl) ether (decabromodiphenyl ether),' final environmental draft of May 2004." Adopted by the SCHER during the 4th plenary of 18 March 2005.

⁶ European Commission Joint Research Center, 2005. Addendum to the May 2004 Environmental Risk Assessment Report for Decabromodiphenyl Ether: Draft 2005.

⁷ *Ibid.*, p. 41.

⁸ UK Department of Trade and Industry. Unofficial Note of the Technical Adaptation Committee on the WEEE and RoHS Directives, Brussels, 19 April 2005. Available at http://www.dti.gov.uk/sustainability/weee/TAC_Unofficial_Note_April05.pdf, viewed August 23, 2005.

to oppose the Draft Decision unless the Commission reconsidered the exemption of Deca-BDE.⁹ The European Parliament followed suit on July 6, 2005 with the same resolution.¹⁰ Despite the objections of members of the European Parliament, the European Council voted in favor of the exemption on September 2, 2005¹¹. The Draft Decision to exempt Deca-BDE was then forwarded back to the Commission, adopted, and published on October 13, 2005¹². The exemption of Deca-BDE will remain in effect for 5 years. Because of the controversy surrounding Deca-BDE, members from the European Union continue to meet on a quarterly basis to review new data and studies on Deca-BDE and the Commission may rescind the exemption at any point in the future.

Departments of Ecology and Health Communication with the European Commission

Much of the proceedings of the European Union are closed sessions, meaning that official transcripts are unavailable to the public. As a result, interpretations vary in how different branches of EU government have responded to the exemption of Deca-BDE from the RoHS. Throughout this process, Ecology and Health has kept in contact with Robert Donkers, a delegate of the European Commission to the U.S. He has articulated that the Commission will continue to monitor Deca-BDE closely and may withdraw the exemption at any time in the future if new findings arise that show Deca-BDE, or its products, to be harmful to humans or the environment.

⁹ European Parliament, Committee on the Environment, Public Health and Food Safety. Motion for a Resolution, B6-0392/2005. Posted June 22, 2005.

¹⁰ European Parliament. "Flame Retardants: MEPs Challenge the Commission." From the EP Daily Notebook July 6, 2005.

¹¹European Brominated Flame Retardant Industry Panel. "Status of Proposed RoHS Exemption for Deca-BDE, 14 September, 2005. Available at <http://www.ebfrip.org/publications.html>, viewed October 13, 2005.

¹² European Commission Decision 2005/717/EC, 13 October 2005. Published in the Official Journal of the European Union, October 15, 2005.